THE BUSINESS CASE FOR DESIGN FOR THE ENVIRONMENT FOR MEDICAL DEVICE MANUFACTURERS

WORKSHOP FINAL REPORT
September 2005

Design For The Environment (DfE) Workshop
Boston, Massachusetts
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Prepared by:

Commonwealth of Massachusetts
Executive Office of Environmental Affairs
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Table of Contents

Tables

Executive Summary

The Massachusetts Executive Office of Environmental Affairs (EOEA) and the Office of Technical Assistance (OTA) convened a workshop on June 21, 2005 on the topic "The Business Case for Design for the Environment for Medical Device Manufacturers." The workshop was designed to enhance the competitiveness of medical device manufacturers in Massachusetts by assisting them in anticipating and proactively responding to marketplace pressures to improve the environmental attributes of products. The medical device industry is an important and stabilizing influence on the Massachusetts economy, and includes key linkages to the research community, biopharma, and traditional manufacturers, such as metal finishing, plastics and electronics.

OTA was successful in arranging co-sponsorship of the workshop by key trade associations including MassMEDIC, the Greater Boston Chamber of Commerce, and the Associated Industries of Massachusetts (A.I.M.). Thirty individuals from twenty-four (24) companies, business organizations, academia and federal and state government participated in the workshop. The target audience of the workshop was executives, research and development staff and senior business managers, as well as product designers and environmental, health and safety professionals. The agenda included a 45-minute Executive Session, which was followed by a longer technical session that included multiple speakers and case studies.

Executive Session

The executive session was led by Dr. Patrick Eagan, a professor at the University of Wisconsin-Madison with more than ten years of Design for the Environment (DfE) experience consulting to medical device manufacturers and healthcare organizations. He provided executives with an understanding of DfE principles, and a review of regulatory, marketplace and operational drivers that are forcing leading manufacturers to integrate environmental issues into business operations and product design. According to Dr. Eagan, the key is to understand where global environmental regulations and public concerns are heading, and make strategic business and product decisions to seize emerging opportunities and avoid risks that new products will soon be obsolete or further regulated. He cited GE's "Ecomagination" campaign as illustrative of a proactive corporate approach designed to create revenue for the company.

Technical Session

The technical session included a more detailed DfE presentation by Dr. Eagan, case studies, remarks by Environmental Affairs Secretary Ellen Roy Herzfelder on Massachusetts policy initiatives, and guidance on emerging marketplace drivers for DfE.

Dr. Eagan's presentation introduced the concept of industrial ecology, which he defined as the fundamental intellectual framework underlying the application of sustainable principles in the workplace. Companies that follow these principles will, in theory: (a) design product life cycles, rather than products; (b) select materials using different criteria than employed in the past; and (c) be concerned about the fate of the product after its useful life. Dr. Eagan also provided a review of DfE tools used in the design of new or modified products, and examples of products

designed to meet certain environmental criteria, such as toxics use reduction, energy conservation, or enhanced recycling.

Two companies presented success stories on how they have incorporated DfE elements into their product design. Theresa Tiernan of Bayer Healthcare, LLC described how Bayer proactively identifies environmental, health and safety issues and designs products and operations to minimize the impacts. The many benefits of Bayer's DfE program were clearly described. Al Iannuzzi of Johnson and Johnson began by discussing the marketplace and corporate drivers that motivated the company to develop a DfE program. He then described the major components of the program, which include its policy, a comprehensive DfE toolbox, and a formal mechanism for reporting of environmental performance against product stewardship goals. Iannuzzi also provided a number of examples of specific Johnson and Johnson products developed or redesigned by the company that utilized DfE and saved money, avoided regulatory challenges and met customer driven requirements.

Of the many questions raised by attendees during the technical session, people sought a better understanding of the role of FDA regulations and potential enforcement in stifling the redesign of FDA approved products. It was apparent from the discussion that additional guidance in this area is clearly needed.

EOEA Secretary Herzfelder delivered a presentation on Massachusetts policy initiatives to streamline permitting and promote performance-based environmental standards. Herzfelder explained how the state's first-in-the-nation proposal to streamline environmental requirements for biotechnology facilities is illustrative of EOEA's efforts to identify business sectors where new and innovative approaches to permitting and environmental protection can prove effective. She extended an offer to the workshop participants to work cooperatively with her agencies, such as the Department of Environmental Protection (DEP) and OTA, on a regulatory streamlining effort similar to that for the biotech sector that involves the development of policies, regulatory revisions and voluntary initiatives to strengthen both the business climate for the medical device sector and the natural environment in the Commonwealth.

Following Secretary Herzfelder's remarks, Sarah O'Brien of Hospitals for a Healthy Environment (H2E) and Stephen Greene, an environmental consultant, described current and emerging compliance and marketplace drivers. O'Brien outlined the group purchasing process, and described how Group Purchasing Organizations (GPOs) are beginning to evaluate environmental criteria in their assessment and selection of products for healthcare facilities. Greene described how the EU environmental directives prohibiting certain chemical constituents or requiring take-back or recycling are influencing medical device manufacturers in direct and indirect ways. He indicated that, in essence, the EU has become the de facto standard setter for product environmental regulations.

Next Steps

Based on the discussions at the workshop and follow-up conversations with key stakeholders in government and the private sector, EOEA and OTA have identified a number of short- and long-term steps that support Massachusetts' commitment to new and innovative environmental

policies, streamlined permitting, and performance-based standards that will enhance the competitiveness of the medical device sector. OTA is currently considering the following activities as part of its FY06 workplan:

- Collaborate with DEP on evaluating and implementing environmental regulatory streamlining for the medical device sector. This will include developing a Regulatory Guidance Document to provide regulatory certainty for the sector through all stages of product development.
- Compile DfE resources and tools, and conduct training to distribute the information to R&D, manufacturing, and product design professionals in the sector.
- Enhance OTA's on-site technical assistance capacity for this sector.
- Expand partnership opportunities with business, state agencies and NGOs.

Longer-term activities that have been identified include:

- Develop case studies highlighting DfE in the Medical Device Sector
- Conduct additional training on the EU Environmental Directives for the Medical Device Sector
- Design an on-site training presentation for marketing, sales and company executives at medical device manufacturers
- Work with FDA and other states (e.g., Minnesota) to clarify the relationship between the redesign of products and processes and the FDA regulations and GMP process, and develop and distribute guidance
- Meet with FDA representatives to explore the possibility of developing a workshop on FDA Quality Management System Regulations and DfE

For additional guidance or to obtain copies of the workshop materials, please contact the OTA project leader, Dr. John Raschko (john.raschko@state.ma.us).

I. Background

The Massachusetts Executive Office of Environmental Affairs (EOEA) and the Office of Technical Assistance (OTA) convened a workshop on June 21, 2005 on the topic "The Business Case for Design for the Environment for Medical Device Manufacturers." The workshop was designed to enhance the competitiveness of medical device manufacturers in Massachusetts specifically by assisting them with their in anticipation of and response to marketplace pressures to provide more environmentally friendly products. The medical device industry is an important and stabilizing influence on the Massachusetts economy, and includes key linkages to the research community, biopharma, and traditional manufacturers, such as metal finishing, plastics and electronics. For more information about the medical device sector's influence on the Massachusetts economy, see the report [1] by the Donahue Institute of the University of Massachusetts, which is available on the MassMEDIC Association's web site at www.MassMEDIC.com.

The workshop topic was selected based on the results of a Focus Group conduced by OTA in June 2004. This meeting with environmental professionals employed at medical device manufacturers explored the environmental issues, challenges and costs associated with the medical device sector in Massachusetts. Design for the Environment (DfE) resources, tools, and best practices were identified as a priority topic at that meeting.

The 2005 OTA workshop was designed to introduce business models that have successfully integrated DfE principles into operations, and identify the benefit of DfE in product design. The target audience of the workshop was executives, Research and Development (R & D) staff and senior managers, as well as product designers, environmental, health and safety professionals and representatives from companies in the supply chain. In an effort to attract senior level executives to the workshop, the agenda included an Executive Session, led by Dr. Patrick Eagan of the University of Wisconsin-Madison, which was followed by a Technical Session that included multiple speakers and case studies.

II. Co-Sponsors and Outreach

OTA was successful in gaining the co-sponsorship of a number of Massachusetts trade associations. Co-sponsors included:

- **MassMEDIC –** the trade association for the medical device industry in Massachusetts. It includes over 300 members - manufacturers, product developers, suppliers, research institutions and academic health centers. They advocate industry positions at the federal and state government levels, and conduct numerous informational seminars, conferences and issue briefings aimed at bringing the region's medical device community the latest and best information on policies and trends impacting the sector.

[1] **Medical Devices: Supporting the Massachusetts Economy:** A Report by the Donahue Institute, University of Massachusetts, May 2004

- **Greater Boston Chamber of Commerce -** The Greater Boston Chamber is a broad-based association representing more than 1,700 businesses of all sizes from virtually every industry and profession in the region. They provide leadership in creating a healthy climate for economic development and job creation.
- **Associated Industries of Massachusetts -** With over 7,600 members from all industries, A.I.M. works on behalf of employers to improve the Massachusetts business economy. A.I.M. is also the Employer's Resource, providing services to member companies in the areas of human-resource management, employment law, employee training and education, environmental compliance, and energy.

These groups publicized the workshop on their websites, and distributed electronic newsletters that mentioned the event. In addition to this broad outreach effort, direct hard-copy and electronic mailings were sent to targeted members and to medical device representatives with whom OTA has developed a relationship. This group received multiple emails from OTA, including a pre-workshop survey and targeted invitations to the event. Registration forms were placed on the OTA website, and registrants faxed the completed forms to OTA.

III. Attendance at the Workshop

Thirty individuals from twenty-four (24) companies, business organizations, academia, and federal and state government participated in the workshop. Participants included attendees, speakers and co-sponsors. Medical device companies and organizations represented at the workshop included:

- Analogic
- Aware Technology
- Bayer Healthcare
- Clinica World Medical Device & Diagnostic News
- CYTYC Corporation
- enLabel Global Services
- Helbling
- Johnson & Johnson
- MassMEDIC
- Philips Medical Systems
- Smith & Nephew
- Steris Isomedix Services, Inc.
- TNCO, Inc.
- TriVirix
- UMass Amherst

IV. Workshop Presentations and Discussion

The workshop was organized into an Executive Session, followed by a Technical Session. Dr. Patrick Eagan, Ph.D., P.E., was the keynote speaker for both sessions. The speaker presentations and related discussions are summarized below. The workshop Agenda is included in Appendix 2, Speaker Biographies are available in Appendix 3, and available copies of the presentations are provided in Appendix 4.

A. Executive Session

The session was convened by James Stergios, Acting Chief of Staff at EOEA, and Thomas Sommer, President of MassMEDIC. Mr. Stergios welcomed the participants and applauded their environmental efforts and economic achievements. He described EOEA's "lean and green" regulatory agenda and its efforts to streamline regulations, develop performance-based standards and provide assistance in supporting both environmental protection and economic expansion. Mr. Sommer welcomed attendees, and introduced MassMEDIC, describing it as the largest medical device association in the nation. Sommer noted that while MassMEDIC has worked collaboratively with many agencies within the Commonwealth, this was the first effort with EOEA, which he described as an "important start" in building a stronger relationship.

Following these welcoming messages, Dr. Patrick Eagan, a professor at the University of Wisconsin-Madison and DfE consultant, began his interactive presentation entitled "Building Business Value thru Industrial Environmental Performance." The talk was based on insight and generalization from over twelve years of design for the environment tool development and business application, which includes work with Johnson & Johnson and the healthcare sector. According to Eagan, the relationship between business value and environmental value was framed by three main support systems:

1. Business Analysis – Lean Manufacturing, Quality programs, Performance
2. Environmental Analysis – Lifecycle Inventory and Life Cycle Assessment (LCA) of products
3. Improvement Response – LCA of materials, Hazardous materials, equipment selection, operating practices, and logistics improvements

Eagan spoke to the importance of describing DfE principles and goals using quality, productivity and efficiency language. For example, Eagan emphasized DfE as a necessary tool that creates business value through integration with quality management processes, such as Six Sigma and meeting customer expectations/requirements. He made the point that "quality is not conformance to specification, rather it is meeting customer requirements." Several questions he then posed to the audience were: "Do you know your customers?" and "Do you have the capability to add environmental attributes to your design process?" Dr. Eagan

Points To Consider

What does your customer think about the environment? How do you know?

Do they assume that you are in full compliance with all relevant environmental regulations?

Do you know what Environmental Performance is? Does your supply chain know?

described the changing business landscape by summarizing the European Union (EU) environmental directives, and the rapidly developing Asian and European marketplace for environmental products. He discussed how DfE is helping to make the connection between business and the environment. To illustrate this point, he noted that the recent series of commercials by General Electric for "Ecomagination" (see http://ge.ecomagination.com/html) suggests that large, successful companies are increasingly viewing "green products" as business opportunities rather than niche markets. Finally, he spoke to the need for executives to track and stay ahead of emerging issues, such as pharmacology, ecotoxicity, and nanotechnology concerns in the personal care and pharmaceutical product (PCPP) sector. The key, said Eagan, is to understand where global environmental regulations and public concerns are heading and make strategic business and product decisions to seize emerging opportunities and avoid risks that new products will soon be obsolete or further regulated.

B. Technical Session

This session consisted of a more detailed DfE presentation by Dr. Eagan, several case studies, remarks by Environmental Affairs Secretary Ellen Roy Herzfelder, and presentations on DfE Drivers.

1. DESIGN FOR THE ENVIRONMENT: WHERE'S THE GREEN AND GOLD? – DR. PATRICK EAGAN, UNIVERSITY OF WISCONSIN-MADISON

Dr. Eagan delivered a presentation that described available tools for successfully implementing a DfE program.

He first introduced the concept of industrial ecology, which he defined as the fundamental intellectual framework underlying the application of sustainable principles in the workplace. Examples of the principles included:

- Designing industrial ecosystems (e.g., waste = raw material for other processes)
- Product life extension (e.g., durability, reuse, remanufacture)
- Design for the Environment (e.g., adaptation, eco-efficiency)
- Industrial metabolism (e.g., energy and material flows, closed loop systems)

Companies that follow these principles will, in theory: (a) design product life cycles, rather than products; (b) select materials using different criteria than employed in the past; and (c) be concerned about the fate of the product after its useful life.

As an example, Dr. Eagan described how DfE tools have been used to evaluate the manufacture of soap. He also provided illustrations and graphics of other DfE tools that have been used by various industries. These included:

- Checklist for the design of joining techniques regarding recycling/upcycling
- Energy consumption for raw material production
- Life cycle inventory for several materials
- Life cycle inventory for plastic packaging
- Full process assessment matrix
- Graphical representations of the life cycle impacts of several materials

He highlighted several examples of successful products that were designed, or redesigned, to meet environmental criteria. He also shared the following observations and lessons learned:

- Don't create an unsolvable problem for a designer
- We never seem to have the right data or information – use what you have
- Decision-makers are more interested in information than tools
- DfE capability exists in many multi-national companies, but may not be used consistently
- Education focusing on different levels of management is necessary
- Move from cutting costs to exploiting innovation
- Customers can drive DfE activity through quality programs
- Connection to business strategy is critical
- The supply chains are growing very close to the OEM due to e-commerce, which also brings environmental risk
- The notion of a potentially abrupt environmental disaster is hard to communicate to business people

Discussion

The discussion centered largely on the role of Food and Drug Administration (FDA) regulations and potential enforcement in stifling the redesign of FDA approved products with validated Good Manufacturing Practices (GMPs). It was acknowledged by many audience members that the "threshold" is unclear when a company should seek FDA reapproval for a process change. For example, one participant noted that a company was fined by the FDA and subject to a million dollar lawsuit because it changed cleaning agents for its equipment without receiving FDA approval. Another audience member mentioned that the FDA provides examples of letters on its website to Chief Executive Officers (CEOs) on these issues, but our subsequent review of the web site found that it had not been updated since 1997.

The general sense of the audience was not to make significant or "threshold" changes to an FDA approved process unless or until the product itself is being redesigned or retooled.

FDA – A KEY PLAYER IN DFE?

Despite extensive efforts on the part of OTA and its consultant, we were unable to obtain targeted guidance to address the perception that time and costs associated with FDA compliance act as an impediment to pollution prevention-oriented changes for existing products, such as chemical substitution, process reengineering, and packaging modifications. FDA does provide some documents that are useful in understanding the regulations and its inspection process, but it is very difficult to obtain targeted information or examples of what does or does not trigger the FDA revalidation process. An "I know it when I see it" or "I know it when there is a problem with the product" attitude prevails. As a result, companies are hesitant to institute changes that benefit the environment unless: (a) a product is being reengineered for other reasons; or (b) the redesign is clearly tangential to the product (e.g., packaging that does not come into contact with the product).

Guidance documents that provide some general guidance and insight include the following:

- FDA Guide to Inspections of Quality Systems (1999)
- FDA Medical Device Quality Systems Manual: A Small Entity Compliance Guide (1999) (see www.fda.gov/cdrh/dsma/gmpman.html)
- FDA Quality System Regulation Part 820 – Document and Change Control (see www.fda.gov/cdrh/qsr/09docnt.html)
- FDA Quality System Regulation Part 820 – Design Control (see www.fda.gov/cdrh/qsr/03desgn.html)

2. CASE STUDY PRESENTATION – THERESA TIERNAN, BAYER HEALTHCARE, LLC

Theresa Tiernan, Health, Environment and Safety (HES) Manager, provided a thoughtful and articulate description of Bayer's integration of environmental, health and safety issues into its design of products. Ms. Tiernan discussed the criteria against which Bayer evaluates potential environmental impacts (e.g., prohibited chemicals, chemicals that may trigger permit exceedances, packaging restrictions) and safety impacts (e.g., hazardous materials, personal protective equipment, ergonomic concerns, special storage considerations). She then led the audience through their Product Development/ Launch process illustrating "where" EHS issues are addressed in the product design process and "how" Bayer tries to "design out" potential deleterious or harmful impacts. Bayer has found great success in following this formalized process, which utilizes checklists during each phase to ensure a proactive approach. Examples of some EHS Proactive Actions that are part of Product Development/Launch at Bayer are summarized in Table 1 below.

Table 1: Proactive DfE Actions During Product Development/Launch at Bayer

Feasibility	According to Tiernan, it is key to train on DfE and have the support of "R&D, marketing, and engineering." A "master list" of resources and links for high hazard and highly regulated materials has been developed for scientists and product designers. EHS signs-off on all internal manufacturing Standard Operating Procedures (SOPs)
Product Specifications	Includes permit modifications, facility modifications and engineering controls, and risk assessment for chemical, biological, radioactive or physical hazards
Product Development	EHS plays a role in review of production SOPs, employee training, occupational safety reviews, waste management determinations, and outside supplier reviews, among other measures
Manufacture	Lean manufacturing
Sales/Support	EHS plays a role in addressing customer questions regarding environmental and safety issues; assists with logistics or restrictions; addresses expired product disposal costs; and monitors worldwide regulatory trends and emerging issues.

Tiernan provided the audience with an honest assessment of both the challenges and the benefits of pursuing proactive product stewardship goals. Challenges included: (a) overcoming the perception that EHS is a bottleneck to product development timelines; (b) building relationships with key internal stakeholders such as project managers and marketing/sales; (c) difficulty of tracking issues worldwide; and (d) quantifying financial advantages, such as removing a toxic component.

The extensive list of benefits realized by their approach included:

- Improved safety and environmental regulatory compliance
- Adequate capital/expense planning for internal improvements needed to manufacture goods

- Reduced packaging costs/duties
- Improved time to market (i.e., avoid unanticipated challenges)
- Increased marketability of goods (e.g., Europe, Asia, GPOs for healthcare)
- Waste reduction for manufacturer and/or customer
- Reduced risk

3. CASE STUDY PRESENTATION – AL IANNUZZI, JOHNSON & JOHNSON

Al Iannuzzi, Ph.D., Executive Director, WorldWide Environmental Affairs delivered an excellent presentation on Johnson & Johnson's (J & J) DfE program. First, he described the myriad of questions about product stewardship that the company receives from diverse customers and consumers from all over the world. Examples are included in the adjacent text box.

Questions J & J Customers and Consumers are Asking

Where does your packaging come from?

Does the corn in baby powder come from genetically modified corn?

Is there PVC in your product?

Second, he described the types of specific marketplace drivers that have led Johnson & Johnson to embrace a formal DfE program:

- Shareholder pressures to remove PVC from products
- European Union bans on phthalates
- Take back obligations under the European WEEE Directive
- Restrictions on use of metals and brominated flame retardants
- Healthcare purchasing organizations considering use of purchasing screens
- State mercury bans and product restrictions

In response to these pressures, J & J has committed to DfE and developed a DfE toolbox to assist company employees in understanding and implementing the program. The toolbox includes:

- A list of questions to consider during the concept phase, which are linked to various white papers and guidance
- A chemical/material search tool so that designers can easily access key information about materials they are contemplating
- Product questions, which help identify design opportunities
- Packaging tools

J & J rolled out its DfE policy and tools in 2000. Corporate Headquarters provided worldwide training and made it clear that Research and Development personnel must "own" the program. Additionally, all applicable facilities are audited against the company's DfE principles to "make sure that implementation of the policy is more than a paper exercise to appease corporate," said Iannuzzi.

J & J also developed "Healthy Planet 2010 Goals," which include certain Product Stewardship goals, such as the take back of electronics and the elimination of certain high priority chemicals. The corporate goal is to eliminate environmental, health and safety issues from products by incorporating DfE and anticipating potential future product issues. According to Iannuzzi, they carefully track international regulatory trends and scientific studies in order to stay ahead of the

curve. Nanotechnology and issues associated with the metabolites of PCPPs are topics that they are currently tracking.

Finally, Iannuzzi provided a number of examples of specific Johnson & Johnson products developed or remanufactured by J & J that utilized DfE and saved money or avoided regulatory challenges.

Discussion

There was an interesting discussion following Iannuzzi's presentation that centered on four key themes first raised by Dr. Eagan. First, audience members were interested in whether Johnson & Johnson sought FDA re-approval for the remanufactured parts and the carrying case redesign example that he presented. In these cases, FDA revalidation was not sought because there was no potential impact on the FDA approved product, but Iannuzzi provided examples (e.g., elimination of PVC from a product packaging, chemical substitution) where Johnson & Johnson would likely seek FDA approval. Second, Iannuzzi stressed the "business" value created by the DfE program. In response to a question about corporate drivers for DfE, Iannuzzi encouraged the audience to review the company's annual sustainability report, which can be found at www.jnj.com/community/health_safety/publications/index.htm, and recommended the Six-Sigma process. Third, Iannuzzi stressed the need to develop performance metrics and hold people accountable for achieving company standards. Johnson & Johnson has a mature and rigorous performance measurement program, which includes the use of a graphical environmental dashboard by all divisions worldwide. There are approximately 21 sustainability indicators in 9 categories on the dashboard. Any indicator in "red" indicates sub par performance. "The value of this dashboard cannot be overstated," said Iannuzzi. "Executives do not want a red light on their dashboard." Finally, Iannuzzi stressed the need to know your customers and to work closely with suppliers to find out what goes into their products. Audits, certifications and declarations are here to stay.

Key J & J Findings

- ***DfE programs create business value***
- ***Need to develop Performance Metrics and hold managers accountable***
- ***Need to know your customers and work closely with suppliers***

4. PRESENTATION – ELLEN ROY HERZFELDER, EOEA

The Secretary of the Executive Office of Environmental Affairs (EOEA), Ellen Roy Herzfelder, joined the meeting and welcomed all attendees. She presented the agency's regulatory policy goals and commitment to streamlined regulations, which are organized around environmental outcomes for specific business sectors and focus on the front-end process. "Our commitment to streamline permits and utilize performance-based or permit-by-rule standards make better use of resources for the state and provide consistency and predictability for the regulated community," said Herzfelder. The state's first-in-the-nation

"Our commitment to streamline permits and utilize performance-based or permit-by-rule standards make better use of resources for the state and provide consistency and predictability for the regulated community."

EOEA Secretary Herzfelder

proposal to streamline environmental requirements applicable to biotechnology facilities is illustrative, said Herzfelder, of her office's efforts to identify business sectors where new and innovative approaches to permitting and environmental protection can prove effective. She extended an offer to participants representing the medical device sector to work cooperatively with her agencies, such as the Department of Environmental Protection and the Office of Technical Assistance, on a regulatory streamlining effort similar to that for the biotech sector that involves the development of policies, regulatory revisions and voluntary initiatives to strengthen both the business climate and the natural environment in the Commonwealth.

5. PRESENTATION – SARAH O'BRIEN, HOSPITALS FOR A HEALTHY ENVIRONMENT

Sarah O'Brien, Champion Coordinator, described Hospitals for a Healthy Environment (H2E), a not-for profit organization whose mission is to help healthcare facilities enhance work place safety, reduce waste and waste disposal costs, and become better environmental stewards and neighbors. H2E has been working with the seven major Group Purchasing Organizations (GPOs) listed in Table 2, which together had a combined purchasing of $57 billion in 2003. O'Brien provided insight into the group purchasing process (e.g., specifications, contracts, negotiations) and described H2E's role in assisting the GPOs to look at their contracts with vendors and identify environmental improvement opportunities.

Table 2: GPOs Partnering with H2E

GPO	Website
Amerinet	www.amerinet-gpo.com
APS (Associated Purchasing Services)	www.apskc.org
Broadlane	www.broadlane.com
Consorta	www.consorta.com
MedAssets HCA	www.medassets.com
Novation	www.novationco.com
Premier	www.premierinc.com

H2E's work includes educating GPOs with respect to environmental issues (e.g., the EU Environmental Directives); hosting workshops and teleconferences for healthcare vendors; suggesting additional environmental inquiries for GPO vendor surveys; connecting alternative vendors to purchasers and physicians who may be uncomfortable with new products; and providing guidance to GPOs with respect to appropriate criteria for product review. It is clear that cost and quality are still the dominant criteria; however, GPOs want products that comply with applicable international, federal, or state standards, and they will select a "green" product when competing products have comparable price and quality. Consequently, it is evident that the focus on the

Healthcare Purchasing is a DfE Driver

While cost and quality are dominant criteria –

- ***GPOs want products that comply with applicable international, federal, or state standards.***
- ***GPOs will select a "green" product when competing products have comparable price and quality.***

environmental aspects of healthcare products by the GPOs can be a driver for medical device manufacturers to adopt DfE in their product development and manufacturing operations.

While it is early in the process of "greening" healthcare purchasing, the process that GPOs will follow in the future is likely to include:

1. Requesting environmental disclosures from vendors
2. Working with non-governmental organizations (NGOs), such as H2E, and experts to identify acceptable alternatives
3. Considering product restrictions, as necessary and appropriate.

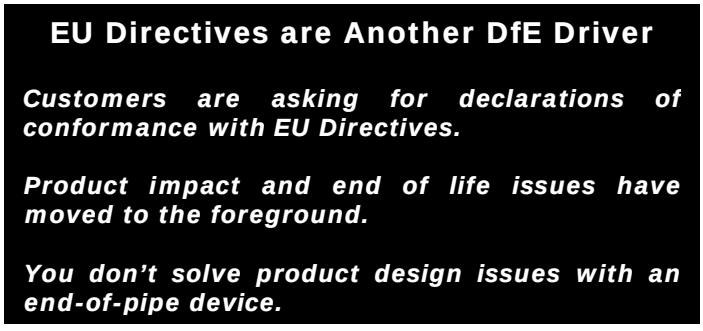
Discussion

The audience was interested in gauging the status of the GPO "greening" trend and determining whether the use of environmental criteria will employ a rational assessment scheme. For example, the question was asked "Will GPOs simply "ban" certain materials, such as PVC or latex, or will they distinguish between the use of these materials and contact with the skin/body, and the use of these materials where there is no risk of human exposure?" O'Brien agreed that broad schemes or prohibitions may not be appropriate. With respect to the extent of the greening trend, O'Brien noted that nearly 90 hospitals are mercury free and certain hospital organizations, such as Kaiser Permanente, are leaders in the sector.

6. PRESENTATION – STEPHEN GREENE, HOWLAND AND GREENE

Stephen Greene provided a brief overview of key European Directives and Policies that are impacting products, focusing on the Restriction of Hazardous Substances (RoHS) and Waste Electronics and Electrical Equipment (WEEE) Directives. He indicated that the EU has become the de facto standard setter for product environmental regulations. Worthy of a half-day workshop in and of itself, Greene helped the audience navigate the complex web of directives and guidance. His slide "Cutting to the Chase" said it best:

- This is not business as usual
- We are dealing with a new paradigm
- This is a new game with new rules and new team members
- Medical device manufacturers may be currently exempt from RoHS, but your supply chain is likely to force you to comply



Greene emphasized a key point of the day, which is that the sales of medical devices are ultimately driven by customer demands, and customers are now asking for declarations of conformance with EU Directives. He also suggested that if an audience member is unconvinced that DfE is simply a cost of doing business internationally, then perhaps they should ask their accounting firm. He noted, for example, that FASBE (Financial Accounting Solutions for Business and Education) has already issued guidance on how to account for costs associated with WEEE compliance. Greene also answered a number of questions concerning WEEE compliance. He reminded the audience that the

use of the WEEE "crossed out wheelie" bin starts August 13, 2005 for products put on the market, and that's just the beginning. Manufacturers/vendors must register under WEEE and the logistics of that decision require some serious thought and consideration. Finally, Greene encouraged the audience to track the emerging directive known as REACH (Registration, Evaluation, and Authorization of Chemicals), which is likely to affect medical device manufacturers, directly or indirectly, in ways similar to RoHS.

V. Workshop Wrap Up/Summary

Paul Richard, Director of OTA, thanked the speakers, co-sponsors and attendees for their efforts and attention. "This workshop is part of a multi-year effort on the part of OTA and EOEA to understand the key environmental issues in the Massachusetts medical device sector and develop environmental training, information and guidance to create business value for the sector." Richard indicated that OTA could help medical device companies access a number of state resources, such as workforce development funds and research assistance in the area of green chemistry through the University of Massachusetts (UMass) system. He also identified potential "next steps," such as on-site training programs, a workshop focused on FDA issues, and development of case studies. Some of these potential ideas are described below. An on-line survey asking respondents to rank these ideas was sent to workshop attendees and the responses will guide OTA's development of future assistance to the sector.

VI. Workshop Materials

In addition to copies of the workshop presentations, workshop attendees' packets also contained the following information. These materials are available, upon request, from Dr. John Raschko (john.raschko@state.ma.us) at OTA:

- DfE Resources
  - Case Study on P2 Best Practices in the Surgical and Medical Instruments Sector, Minnesota Office of Environmental Assistance
  - Design for the Environment Guide: Medtronic – A Case Study, Minnesota Office of Environmental Assistance
  - Design for the Environment Bibliography – Dr. Patrick Eagan
  - Design for the Environment Toolkit, Minnesota Office of Environmental Assistance

- Healthcare Purchasing
  - Presentations from the Group Purchasing Organizations (GPOs) Plenary Panel Discussion, "GPOs: Progress Towards Environmentally Preferable Purchasing", CleanMed, April 2004.
  - Environmentally Preferable Purchasing Resources, published by Hospitals for a Healthy Environment (H2E)
  - New Healthcare On-Line Resources

- Materials from OTA's June 2004 Medical Device Focus Group
  - Issues Paper/Background Material to the Focus Group Meeting
  - Final Report - Summary of Discussions, Findings and Next Steps
  - Genzyme presentation, "Alcohol Waste Management – From Sewer Discharge to Recycling"

VII. Post-Workshop Activities

Based on the discussion at the workshop and follow-up conversations with key stakeholders in government and the private sector, the Executive Office of Environmental Affairs and the Office of Technical Assistance have identified a number of short- and long-term steps that support the state's commitment to new and innovative policies that enhance the competitiveness of the medical device sector, streamline and simplify environmental compliance requirements, and enhance environmental protection. Potential steps being considered are listed below. Reviewers and interested parties are encouraged to send their comments, suggestions, and priorities to Paul Richard of OTA at Paul.Richard@state.ma.us.

OTA is currently considering the following activities as part of its FY06 workplan:

- Collaborate with DEP on evaluating and implementing environmental regulatory streamlining for the medical device sector. This will include developing a Regulatory Guidance Document to provide regulatory certainty for the sector through all stages of product development.
- Compile DfE resources and tools, and conduct training to distribute the information to R&D, manufacturing, and product design professionals in the sector.
- Enhance OTA's on-site technical assistance capacity for this sector.
- Expand partnership opportunities with business, state agencies and NGOs.

Longer-term activities that have been identified include:

- Develop case studies highlighting DfE in the Medical Device Sector
- Conduct additional training on the EU Environmental Directives for the Medical Device Sector
- Design an on-site training presentation for marketing, sales and company executives at medical device manufacturers
- Work with FDA and other states (e.g., Minnesota) to clarify the relationship between the redesign of products and processes and the FDA regulations and GMP process, and develop and distribute guidance
- Meet with FDA representatives to explore the possibility of developing a workshop on FDA Quality Management System Regulations and DfE

Appendices

Appendix 1: DfE Workshop Agenda

Executive Office of Environmental Affairs

Office of Technical Assistance

Setting Your Agenda for Environmental Performance:

THE BUSINESS CASE FOR DESIGN FOR THE ENVIRONMENT FOR MEDICAL DEVICE MANUFACTURERS

June 21, 2005

8:00 AM – 12:30 PM

100 Cambridge Street, Boston, MA

Conference Room B, 2nd Floor

8:00 Registration & Continental Breakfast

8:30 Welcome & Introductions

- *James Stergios, Acting Chief of Staff, Executive Office of Environmental Affairs*
- *Tom Sommer, President, MassMEDIC*

8:40 Executive Session - Building Business Value Through Environmental Protection

- *Patrick Eagan, Ph.D., P.E., University of Wisconsin-Madison*
- *Secretary's Perspective - Ellen Roy Herzfelder, Secretary, Executive Office of Environmental Affairs*

9:15 Break

9:30 Design for the Environment: Where's the Green and Gold?

- *Patrick Eagan, Ph.D., P.E., University of Wisconsin-Madison*

10:30 Company Success Stories

- *Safety and Environmental Product Stewardship Initiatives, Theresa Tiernan, Bayer HealthCare LLC*
- *Al Iannuzzi, Johnson & Johnson*

11:40 Drivers for DfE

- *EU Environmental Directives – Stephen Greene, Howland Greene Consulting, LLC*
- *Healthcare Drivers – Sarah O'Brien, Hospitals for a Healthy Environment (H2E)*

12:20 Discussion & Wrap-up

12:30 Adjourn

Appendix 2: Speaker Biographies

THE BUSINESS CASE FOR DESIGN FOR THE ENVIRONMENT FOR MEDICAL DEVICE MANUFACTURERS
June 21, 2005

Speaker Biographies

Ellen Roy Herzfelder
Secretary of Environmental Affairs, Commonwealth of Mass.

Ellen Roy Herzfelder has been successful as an energy entrepreneur and executive, M.I.T. educator, environmental policymaker, and public administrator. Ellen currently serves as the Massachusetts Secretary of Environmental Affairs under Governor Mitt Romney. She is responsible for all environmental matters including regulatory agencies such as the Department of Environmental Protection, Department of Fish and Game, Department of Agriculture and Office of Coastal Zone Management as well as the state parks agency, the Department of Conservation and Recreation, the sixth-largest system in the United States based on acreage. Her major accomplishments to date include a "lean and green" initiative that reduced the timeframe for environmental permit reviews; a parks initiative that merged and reformed two state park systems into one united agency; and an oceans initiative to reform the state ocean regulatory process.

Ellen is an entrepreneur and senior executive from the energy industry. In the 1980s, she co-founded and became Senior Vice President of the Intercontinental Energy Corporation and its affiliates (IEC), a billion-dollar private company that owned and operated large cogeneration power plants. IEC sold electricity to public utilities and procured natural gas and oil from pipeline companies and energy producers in the Gulf of Mexico and Canada, and also developed coal-based power plants in the United States and in China, India and Indonesia.

Ellen was also a founder and senior executive of Environmental Corporation of America, Inc., which teamed with Raytheon and Cogema, the French nuclear company, on a privatization initiative to clean up nuclear waste at DOE facilities. In 2000, Ellen was appointed Senior Lecturer at the Entrepreneurship Center at the M.I.T. Sloan School of Business.

Ellen has a B.A. in Russian Studies from Harvard College (1981), an M.B.A. from the M.I.T. Sloan School of Business (1987), and an M.P.P. from the Harvard Kennedy School of Government (1987).

Thomas J. Sommer
President, MassMEDIC

Tom Sommer was named the first president of the Massachusetts Medical Device Industry Council (MassMEDIC) in October 1996 by the organization's founding Board of Directors. Since that time, he has served as the association's chief executive officer, managing its day-to-day operations and working with medical device industry executives in developing its policy agenda. Since its establishment, MassMEDIC has grown to over 300 member companies – manufacturers and developers of medical products, suppliers, research institutions and academic health centers - and has advanced the public policy interests of the Massachusetts medical device sector on Capitol Hill, Beacon Hill, and before various federal agencies.

Prior to his appointment at MassMEDIC, Mr. Sommer served as a vice president of the Massachusetts Technology Collaborative, where he managed external relations and research activities for this quasi-state agency from 1994-1996. He was vice president for policy and communications of the New England Council, a regional business organization, from 1989-1994.

Mr. Sommer was deputy director of the Massachusetts Office of Federal-State Relations in Washington, D.C. and Boston from 1983-1987, serving as a member of Governor Michael S. Dukakis's senior staff. From 1980-1983, he was a legislative assistant at the National Association of Development Organizations, a Washington-based association of local economic development officials.

Mr. Sommer received his B.A. in political science from Boston College and a master's degree in public administration from the John F. Kennedy School of Government at Harvard University.

Professor Patrick Eagan
Associate Professor, University of Wisconsin-Madison

Patrick Eagan is an associate professor at the University of Wisconsin-Madison, Department of Engineering Professional Development and the Gaylord Nelson Institute for Environmental Studies through which he develops and offers continuing environmental engineering education to practicing professionals. Dr. Eagan has been actively involved internationally in the development of design-for-the-environment tools and education since 1992. He has worked with many companies tailoring educational programs on the emerging topics of environmental awareness, life-cycle management/design-for-the-environment, environmental management systems, and

environmental purchasing. Dr. Eagan recognizes the value of quality concepts and has focused on merging environmental perspectives with quality education programs (e.g. design-for-excellence or six sigma). His favorite industrial ecology projects were the global rollouts of design-for-the-environment curricula at Motorola and Johnson & Johnson. In addition to his research in industrial ecology, his outreach courses include a range of topics including wastewater and stormwater treatment and restoration of water resources. He uses collaborative learning techniques and class exercises to meet his educational goals.

Dr. Eagan is a member of Institute of Electrical and Electronics Engineers Technical committee on Electronics and the Environment and has been active in both national and international symposia. He was conference Co-chair for the 1999 International Symposium on Electronics and the Environment in Boston. In 2000 he was conference co-chair of the international meeting "Electronics Goes Green" in Berlin, Germany and in 2001 was on the program committee and a keynote speaker for the "Going Green" Eco-design meeting in Tokyo. He was conference co-chair for the "Going Green" 2003 meeting in Boston and 2004 again in Berlin.

Al Iannuzzi, Ph.D.
Johnson & Johnson, Executive Director, WorldWide Environmental Affairs

Al is employed by Johnson & Johnson as Executive Director in the WorldWide Environmental Affairs group. Some of his responsibilities include: managing the WW Pharmaceutical group environmental programs, spearheading Johnson & Johnson's Design for the environment program, regulatory outreach initiatives, environmental cost accounting and remediation programs. He also has experience as an environmental consultant and worked as a hazardous waste inspector for the NJ Department of Environmental Protection. Al received his Ph.D. degree in Environmental Policy from the Union Institute & University in Cincinnati where he researched voluntary compliance and self-regulation. He is a Certified Environmental Management System Lead Auditor for ISO14001 and author of the book "Industry Self-regulation and Voluntary Environmental Compliance" (CRC Press, 2002).

Theresa Tiernan
Bayer HealthCare LLC, Health, Environment and Safety Manager

Theresa Tiernan is a Health, Environment and Safety Manager at Bayer HealthCare's Norwood, MA facility, and has been with Bayer for more than ten years. She has 19 years experience in the health, safety and environmental field in the high tech and biotech industries in Massachusetts.

Theresa received a B.S. in Biology from Syracuse University and an M.S. in Environmental Health from UMass Amherst. She is a Certified Industrial Hygienist, Certified Safety Professional, and Certified Biosafety Professional.

Stephen Greene
Principal, Howland Greene Consultants

Stephen Greene is a principal of Howland Greene Consultants, formed in 2005. He specializes in international product environmental requirements and sustainable business practices. He is chair of the Massachusetts Water Resource Authority's Wastewater Advisory Committee, and chair of the Board of WasteCap of Massachusetts

Prior to Howland Greene, he was Corporate Product Stewardship and International Environmental Manager for Polaroid Corporation. He joined Polaroid in 1990 and provided world-wide oversight in the areas of Product Stewardship, Sustainability/ Environmental reporting, and international environmental management. He managed a full range HSE regulatory areas as well as information systems and enterprise integration. He created Polaroid's RoHS Free program for Polaroid's electronic products, integrating electronics take back requirements into the program design. He was active in Industry and Regulatory advisory committees. He was president of the New England Chapter of National Association for Environmental Management, and a participant in Massachusetts working groups on technology, regulatory reform and watershed issues/management where Polaroid's interests were at stake.

Prior to Polaroid, Mr. Greene spent 10 years at Digital Equipment Corporation where he was the Corporate Environmental Manager with worldwide responsibility for about 40 facilities. While at Digital he chaired the Semiconductor Industry Association Environmental Committee among his many external business responsibilities.

Sarah O'Brien
Champion Coordinator, Hospitals for a Healthy Environment

Sarah O'Brien is the Champion Coordinator for Hospitals for a Healthy Environment. She works with Group Purchasing Organizations (GPOs), state environmental departments, manufacturers, service providers, health systems and other large organizations to improve environmental performance and promote H2E's programs. Prior to her arrival at H2E, Ms. O'Brien was a Senior Outreach Associate with INFORM, a national nonprofit organization providing assistance to government agencies, institutions and businesses interested in reducing their purchase of products that contain mercury, lead and other persistent toxic

chemicals. Ms. O'Brien is a member of the National Pollution Prevention Roundtable's Board of Directors, board liaison to that organization's Health Care Workgroup, and has been developing, analyzing and negotiating public policies on a variety of environmental health issues since 1989.

Ms. O'Brien received a BA magna cum laude from Yale College in 1980 and an MA in Anthropology from Temple University in 1985.

Appendix 3: Available Workshop Presentations